

- 36 -

What is claimed is

1. A pharmaceutical composition for sustained release comprising as active ingredient pitavastatin or a pharmaceutically acceptable salt thereof, said composition comprising an inner phase (internal) and an outer phase (external), wherein at least the outer phase comprises at least one matrix former.
2. A composition according to claim 1 wherein the amount of HMG-CoA reductase inhibitor or pharmaceutically acceptable salt thereof is about 5-50 weight % of the composition.
3. A composition according to anyone of claims 1 to 2 wherein the amount of HMG-CoA reductase inhibitor or pharmaceutically acceptable salt thereof is about 1-32mg.
4. A composition according to anyone of claims 1 to 3, wherein the inner phase comprises a matrix former.
5. A composition according to claim 4, wherein the matrix former of the inner phase comprises one or more types of matrix former component having different viscosities.
6. A composition according to claim 5, wherein the matrix former of the inner phase has a viscosity of about 1 to about 500 cps.
7. A composition according to any one of claims 1 to 6, wherein the matrix former of the external phase comprises one or more type of matrix former component having different viscosities.
8. A composition according to claim 7, wherein the matrix former of the external phase has a viscosity of about 100 to about 100000cps.
9. A composition according any one of claims 1 to 8, wherein the matrix former is selected from the group consisting of polyethylene glycol, polyvinylpyrrolidone, polyvinyl alcohol, hydrophilic polymers such as hydroxypropylcellulose, hydroxymethylcellulose, and hydroxypropylmethylcellulose or the like.

**BEST AVAILABLE COPY**

- 37 -

10. A composition according to claim 9, wherein the matrix former is hydroxypropylmethylcellulose (HPMC).
11. A composition according to claim 10 wherein the amount of HPMC as a matrix former is about 1-60 weight % of the composition.
12. A composition according to anyone of claims 1 to 11, wherein said composition comprises a stabilizer.
13. A composition according to claim 12, wherein the stabilizer is magnesium aluminium metasilicate (neusilin).
14. A composition according to claim 12 or 13, wherein the amount of the stabilizer is about 1-15 weight % of the composition.
15. A method of treatment of hyperlipidemia, hypercholesterolemia and atherosclerosis, as well as other diseases or conditions in which HMG-CoA reductase is implicated comprising administering to a patient in need thereof a therapeutically effective amount of a composition according to any one of claims 1 to 14.
16. Use of the composition according to any one of claims 1 to 14 in the manufacture of a medicament for use in the treatment or prevention of a cardiovascular disease, e.g., hypercholesterolemia, hyperproteinemia and /or atherosclerosis.

**BEST AVAILABLE COPY**